

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent Application of:  
Sung Lan Hsia, *et al.*

Confirmation No.: 1083

Application No.: 10/597378

Art Unit: 1651

Filed: July 21, 2006

Examiner: Thane E. Underdahl

For: TOPICAL CO-ENZYME Q10  
FORMULATIONS AND METHODS OF USE

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MS Patent Extension  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT UNDER 37 C.F.R. § 1.705(B)(2)**

Dear Sirs:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration under 37 C.F.R. § 1.705(b)” in the above-identified patent. It is respectfully requested that Applicants be granted a minimum patent term adjustment of **1029 days** and that any calculation after issuance be adjusted accordingly.

2. The patent term adjustment on the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) (“Determination”) that was attached to the Notice of Allowance is **706 days**.<sup>1</sup> Applicants respectfully submit that the determination to date of 706 days of patent term adjustment is in error in that it omits a patent term adjustment credit of 323 (1029 days of Three Year Delay less 706 days of overlap with the 14 Month Delay) days under 37 C.F.R. § 1.702(b), for the reasons discussed below.

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<sup>1</sup> A copy of the PTO’s Patent Term Adjustment history (“PTA history”) available on Public Pair is submitted herewith as Appendix A.

3. The factual bases for the above-adjustment are set forth as follows:

**A. Examination Delays Pursuant to 37 C.F.R. § 1.702 and § 1.703**

Pursuant to 37 C.F.R. § 1.703(f), the period of adjustment of the term of the patent under 37 C.F.R. § 1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704 (the Applicant Delay). In the above-identified patent application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under § 1.703(a)(1) and § 1.702(b) for the reasons set forth below.

**(i) "14 Month Delay" Pursuant to 37 C.F.R. § 1.703(a)(1)**

In accordance with 37 C.F.R. § 1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than 14 months after the date on which the application fulfilled the requirements of 35 U.S.C. §371 in an international application (hereinafter "the 14 Month Delay").

The date on which the instant applicant fulfilled the requirements of 35 U.S.C. §371 is August 21, 2008, which is in agreement with the date indicate by the Office on the Patent Term Adjustment History, enclosed as Appendix A. As shown in the Patent Term Adjustment History, the Office failed to mail an action under 35 U.S.C. § 132 until September 27, 2011. As such, Applicants are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date on which the above-identified application commenced the national phase under 35 U.S.C. § 371(b) or (f), *i.e.*, October 22, 2009, and ending on the date of mailing of an action under 35 U.S.C. § 132, *i.e.*, a non-final Office Action mailed from the Office on September 27, 2011. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is **706 days**, which is in agreement with the period calculated by the Office on the Patent Term Adjustment History, enclosed herein as Appendix A.

**(ii) "Three Years Delay" Pursuant to 37 C.F.R. § 1.702(b)**

Pursuant to 37 C.F.R. § 1.702(b), Applicants are entitled to a period of delay due to the

failure of the Office to issue a patent within three years after the date on which the national stage commenced under of 35 U.S.C. § 371(b) or (f) in an international application (hereinafter “the Three Year Delay”). It is anticipated that the Office will fail to comply with this Requirement. The date on which the national phase commenced under 35 U.S.C. § 371(b) or (f) is July 21, 2006. As indicated in the Notice of Allowance, a patent is projected to issue on May 15, 2012<sup>2</sup>. As such, there is an anticipated delay of at least **1029 days**, based on the period of time beginning on the day after the date that is three years after the date on which the above-identified patent application commenced the national phase under 35 U.S.C. § 371(b) or (f) (*i.e.*, July 22, 2009) and the date that the patent is projected to issue (*i.e.*, May 15, 2012).

(iii) Total Examination Delay Pursuant to 37 C.F.R. § 1.703(f)

As set forth in 37 C.F.R. § 1.703(f), the period of examination delay based on the grounds set forth in 37 C.F.R. § 1.702 is the sum of the period of the 14 Month Delay (706 days) and the maximum period of the Three Years Delay (1029 days), or 1735 days, to the extent that these periods are not overlapping. See *Wyeth v. Dudas*, 580 F. Supp. 2d 138 - Dist. Court, Dist. of Columbia, 2008.

As set forth in 35 U.S.C. § 154(b)(2)(A), the total period of examination delay does not include any periods of overlap between the Three Years Delay period and the 14 Month Delay period. Applicants note that the period of the 14 Month Delay began on October 22, 2009 and ended on September 27, 2011 and the period of the Three Years Delay began on July 22, 2009. Accordingly, the 14 Month Delay and the Three Years Delay overlap between October 22, 2009 and September 27, 2011, *i.e.*, by **706 days**.

In view of all of the foregoing, Applicants submit that the total period of examination delay is the sum of the period of the 14 Month Delay (706 days) and the Three Years Delay (1029 days), minus the overlap (706 days). Accordingly, Applicants calculate that the total period of examination delay is **1029 days**.

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<sup>2</sup> The Determination of Patent Term Adjustment under 35 U.S.C. 154(b) mailed from the U.S. Patent and Trademark Office indicates that the Patent Term Adjustment was calculated based on the assumption that the patent will issue on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice”, *i.e.*, May 15, 2012.

**B. “Applicant Delay” Pursuant to 37 C.F.R. § 1.704(a)**

In accordance with 37 C.F.R. § 1.704(a), the period of adjustment of the term of a patent under §§ 1.703(a)-(c) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application (the Applicant Delay). In the above-identified patent, Applicants have accumulated no Applicant Delay under 37 C.F.R. §§ 1.704(b), (c)(8), or (c)(10).

**C. Calculation of Correct Patent Term Adjustment Pursuant to 37 C.F.R. § 1.702(f)**

As set forth in 37 C.F.R. § 1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays (*i.e.*, 1029 days) reduced by the period of Applicant Delay (*i.e.*, 0 days). Therefore, Applicants submit that the correct patent term adjustment for the above-identified application is **at least 1029 days**, which is the difference between the total period of examination delay (1029 days) and Applicant Delay (0 days). This period of patent term adjustment is not in agreement with the current patent term adjustment calculated by the Office on the Patent Term Adjustment History, enclosed herein as Appendix A.


4. In accordance with 37 C.F.R. § 1.702(b)(2)(iii), Applicants submit that this patent is not subject to a terminal disclaimer.
5. In view of 37 C.F.R. 1.705(b)(2)(iv)(B), Applicants submit that they are unaware of any circumstances during the prosecution of this application that would constitute a failure by the Applicant to engage in reasonable efforts to conclude processing or examination of this application as set forth in § 1.704.
6. In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of at least **1029 days**, and that any calculation after issuance be adjusted accordingly.



**APPENDIX A**  
**Patent Term Adjustment History**  
**as Calculated by the U.S. Patent and Trademark Office**

**Patent Term Adjustment**

Filing or 371(c) Date:	08-21-2008	Overlapping Days Between {A and B} or {A and C}:	0
Issue Date of Patent:	-	Non-Overlapping USPTO Delays:	706
A Delays:	706	PTO Manual Adjustments:	0
B Delays:	0	Applicant Delays:	0
C Delays:	0	Total PTA Adjustments:	706

Patent Term Adjustment History		Explanation of Calculations 			
Number	Date	Contents Description	PTO(Days)	APPL(Days)	Start
80	11-03-2011	Mail Notice of Allowance			0
79	11-03-2011	Office Action Review			0
78	11-03-2011	Office Action Review			0
77	11-03-2011	Office Action Review			0
76	11-03-2011	Office Action Review			0
75	11-03-2011	Issue Revision Completed			0
74	11-03-2011	Document Verification			0
73	11-03-2011	Notice of Allowance Data Verification Completed			0
72	11-02-2011	Reasons for Allowance			0
71	11-02-2011	Interview Summary- Applicant Initiated			0
70	11-02-2011	Examiner's Amendment Communication			0
69	11-02-2011	Allowability Notice			0

64	09-27-2011	Mail Non-Final Rejection	706	12
63	09-26-2011	Office Action Review		0
62	09-12-2011	Office Action Review		0
61	08-29-2011	Office Action Review		0
60	10-20-2010	Information Disclosure Statement considered		0
59	08-22-2011	Non-Final Rejection		0
58	08-04-2011	Reference capture on IDS		0
57	08-04-2011	Information Disclosure Statement (IDS) Filed		0
56	10-20-2010	Information Disclosure Statement (IDS) Filed		0
50	09-10-2008	Information Disclosure Statement considered		0
49	07-21-2009	Information Disclosure Statement considered		0
48	08-04-2011	Information Disclosure Statement considered		0
46	08-04-2011	Information Disclosure Statement (IDS) Filed		0
45	06-27-2011	Preliminary Amendment		0
42	05-09-2011	Case Docketed to Examiner in GAU		0
41	05-02-2011	Case Docketed to Examiner in GAU		0
40	04-27-2011	Case Docketed to Examiner in GAU		0

39	03-31-2011	Case Docketed to Examiner in GAU	0
38	02-18-2011	Preliminary Amendment	0
36	10-20-2010	Information Disclosure Statement (IDS) Filed	0
31	12-07-2009	Preliminary Amendment	0
30	07-21-2009	Reference capture on IDS	0
29	07-21-2009	Information Disclosure Statement (IDS) Filed	0
28	09-08-2009	Change in Power of Attorney (May Include Associate POA)	0
27	09-02-2009	Correspondence Address Change	0
26	07-21-2009	Information Disclosure Statement (IDS) Filed	0
25	09-10-2008	Information Disclosure Statement (IDS) Filed	0
24	04-08-2009	Case Docketed to Examiner in GAU	0
22	12-04-2008	PG-Pub Issue Notification	0
21	12-03-2008	IFW TSS Processing by Tech Center Complete	0
20	09-10-2008	Information Disclosure Statement (IDS) Filed	0
14	09-10-2008	Information Disclosure Statement (IDS) Filed	0
13	09-01-2008	Application Dispatched from OIPE	0
12	08-21-2008	371 Completion Date	0



11	08-26-2008	Sent to Classification Contractor	0
10	08-27-2008	Filing Receipt	0
9	08-27-2008	Notice of DO/EO Acceptance Mailed	0
8	08-21-2008	Additional Application Filing Fees	0
7	08-21-2008	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	0
0.5	01-21-2005	International Filing date	0